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Document Archiving Reporting and Regulatory Tracking System (DARRTS) Data Management and Analysis Modifications Task Order 29

in support of:

Issued to:
SRA International, Inc.

UNDER FEDSIM BPA:
GS-TFMG-BPA-09-0017

The Contractor's Basic GSA Schedule contract is applicable to the Task Order and is hereby incorporated by reference

Issued by:
General Services Administration
Federal Systems Integration and Management Center (FEDSIM)
1800 F Street NW, Suite 3100
Washington, DC 20405

July 12, 2018

Modification PS01

FEDSIM Project Number29021HHM

1.1 ORDER TYPE

The Contractor shall perform the effort required by this Task Order (TO) on a Firm Fixed Price, , Time & Materials and Not To Exceed basis. The work shall be performed in accordance with all sections of this TO and the offeror's General Services Administration (GSA) Multiple Award Schedule (MAS).

1.2 SERVICES AND PRICES

The following abbreviations are used in this price schedule:

CLIN	Contract Line Item Number
FFP	Firm-Fixed-Price
NTE	Not-to-Exceed
ODC	Other Direct Cost
T&M	Time & Materials
QTY	Quantity

1.2.1 ORDER PERIOD

MANDATORY FFP LABOR

CLINs

CLIN	Description	Qty	Unit	Total FFP
0001	Project Management (Task 1)	(b) (4)	(b) (4)	(b) (4)

MANDATORY LABOR CLIN

CLIN	Description	Total Hours	Total NTE LH Price
0002	DARRTS Task Development Labor (Tasks 2-4)		(b) (4)

Labor Category	Hours	Hourly Rate
(b) (4)	(b) (4)	(b) (4)
	(b) (4)	(b) (4)
	(b) (4)	(b) (4)
TOTAL HOURS	(b) (4)	

MANADATORY TOOLS CLIN

CLIN	Description		Total FFP Price
0003	**DARRTS Tool Implementation (Task 3)**	**FFP**	(b) (4)

GRAND TOTAL ALL CLINs **$4,896,442**

1.3 SECTION 1 - SUPPLIES OR SERVICES AND PRICES TABLES

1.3.1 TIME-AND-MATERIALS (T&M)LABOR HOUR (LH) LABOR MIX AND LEVEL OF EFFORT

The labor mix and level of effort specified in the contractor's quote and incorporated into this TO are for estimation purposes. The contractor may reallocate, with prior written approval of the Federal Systems Integration and Management Center (FEDSIM) Contracting Officer's Representative (COR), the number of hours by labor category, within each labor CLIN as needed to effectively manage the project, provided the total funded labor cost and total hours are not exceeded. Any additional labor categories or increases to total hours or increases to ceilings required during performance must be approved by the FEDSIM Contracting Officer (CO) and added to the TO by modification.

1.4 INCREMENTAL FUNDING

1.4.1 INCREMENTAL FUNDING LIMITATION OF GOVERNMENT'S OBLIGATION

Incremental funding in the amount of (b) (4) for CLINs 0001 through 0003 is currently allotted and available for payment by the Government. Additional incremental funding for these CLINs may be allotted and available for payment by the Government as the funds become available. The estimated period of performance covered by the allotments for the mandatory CLINs is from award through *July 11, 2019* unless otherwise noted in Section 1 – Supplies or Services and Prices. The TO may be modified to add funds incrementally up to the maximum of (b) (4) over the performance period of this TO. These allotments constitute the estimated cost for the purpose of Federal Acquisition Regulation (FAR) Clause 52.232-22, Limitation of Funds, which applies to this TO on a CLIN-by-CLIN basis.

2.1 BACKGROUND

In production since January 2006, The Document Archiving, Reporting and Regulatory Tracking System (DARRTS) provides the FDA Center for Drug Evaluation and Research (CDER) users with the ability to receive, manage, track, and report on drug applications. DARRTS delivers major advancements regarding flexibility, integration, and meeting CDER's business requirements. DARRTS helps the FDA provide better reports to Congress on a number of issues, including performance on the Prescription Drug User Fee Act (PDUFA) related goals, Generic Drug User Fee Act (GDUFA) and the Biosimilar User Fee Act (BsUFA).

The Office of Information Management and Technology (OIMT) Systems Division designs, develops, implements, and maintains corporate-wide systems for the FDA as a whole. Using project management and various application development techniques, staff members work closely with FDA Center users to deliver high quality information processing applications. This includes the continued development of the DARRTS Program. The DARRTS Program includes the central DARRTS applications, Data Reporting and Business Intelligence (DRBI), & DARRTS Precedents Tracking (PT).

DARRTS is a component-based, multi-tier enterprise application that is accessed via a web-based interface. The system runs within the Center for Drug Evaluation and Research (CDER) intranet network and is only available to authorized users. DARRTS provides FDA users with the ability to receive, manage, track, and report on drug applications. DARRTS delivers major advancements regarding flexibility, integration, and meeting CDER's business requirements. DARRTS helps the FDA provide better reports to Congress on a number of issues, including performance on the Prescription Drug User Fee Act (PDUFA), Generic Drug User Fee Amendments (GDUFA) and Biosimilar User Fee Act (BsUFA). DARRTS requires specific enhancements in order to assimilate functionality of new application types, support functionality previously processed by legacy applications, and move towards a current, mature, flexible, and extensible technology stack to support growing business needs.

The agency is under very tight review timeframes that are becoming even tighter in GDUFA II. Tighter goals coupled with more receipts in GDUFA I than the program was built to manage will lead to difficulties in the assessment process. Currently, reviews are open-ended unstructured text based narratives which make it difficult, if not impossible, to retrospectively ascertain the current state of product quality among approved applications. Likewise, use of unstructured narratives results in unusually lengthy reviews which renders the review process inefficient and inconsistent. Additionally, there is a need to be able to examine and analyze data retrospectively and provide meta-analysis of data.

2.1.1 PURPOSE

The purpose of this TO is to provide the Food and Drug Administration with modifications to the DARRTS Program as a branch of Precedent Tracking to provide better knowledge management and analysis of data through custom templates, modules, and a data analysis tool. This support

will provide a highly structured data landscape for knowledge management to enhance functionality of the DARRTS environment in an effort to ensure business continuity under BPA GS-TFMG-BPA-09-0017.

2.1.2 AGENCY MISSION

The Food and Drug Administration (FDA) is the Federal agency responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public's health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public acquire the accurate, science-based information they need to use medicines and foods to improve their health.

This TO will support the modification of DARRTS applications, as well as the licensing for Bioinformatics IT Modernization BITM Pilot software and connection to DARRTS of data analysis software.

2.2 SCOPE OF WORK

The Contractor shall provide all resources necessary to accomplish the deliverables described in this TO. The purpose of this TO is to acquire services necessary for modifications of the DARRTS Program as a branch of Precedents Tracking. This work will include modifications required to create structured user interfaces for reviewers to streamline information and facilitate the drug product quality and drug facilities review to provide users with an automated tool to log, track, manage, and report for specific quality/ facility reviews referenced in the application review process. Additionally, a software package will be incorporated into the existing DARRTS Program to provide retrospective review analysis of data and the ability to run meta-analysis of data.

Modifications to DARRTS will be executed in four areas. These include:

a. Office of Pharmaceutical Quality structured data modifications to allow better knowledge management
b. Oncology Center of Excellence (OCE) Office of New Drugs, Office of Pharmaceutical Quality, Office of Surveillance and Epidemiology, Office of Generic Drugs Regulatory Automation Tool
c. Office of New Drugs including Safety, Labeling and Assessment reviews streamlined with structured data modifications
d. Oncology Center of Excellence (OCE) data layer analysis tool and BITM Pilot licensing

Modifications to DARRTS will require executing requirements, design, development, testing and implementation. Prioritization of modifications will be determined through collaboration between the business and IT project teams with final approval provided by the DARRTS Technical Control Board (TCB), Change Control Board (CCB) and/or the DARRTS PM. All

changes to the schedule are at the discretion and direction of the TPOC. As with other development work, the Contractor shall perform analysis, gather requirements, design, develop, test, migrate data, provide necessary support, and implement prioritized modifications.

2.3 CURRENT INFORMATION TECHNOLOGY (IT) ENVIRONMENT

DARRTS is a component-based, multi-tier enterprise application accessed via a web interface. The system runs within the FDA CDER intranet network and is only available to authorized users. The system has a three-tiered architecture. The user interface is browser-based and supports using Microsoft Internet Explorer 11(with tabbed browsing disabled). There is a continuously evolving requirement that the user interface will have to support current and future versions of Internet Explorer, and new browsers, as and when the FDA approves the versions for use. The user interface is implemented in Java and uses Oracle Application Development Facility User Interface X (ADF/UIX), a newer version in ADF Java Server Faces (ADF/JSF), Spring, or its equivalent as approved by FDA. Its persistence layer framework is implemented with object-relational mapping tools, such as Oracle BC4J, Spring Data, Hibernate, or its equivalent, as approved the database is an Oracle database. Documentum, or its equivalent as approved by FDA, is used as a data store for the archival storage and retrieval of official FDA business communications. Business rules are implemented using the open source product Drools, or its equivalent as approved by FDA. The system architecture was reviewed by the Technical Review Board of the Office of the CIO for consistent use of tools and for consistency with the FDA Enterprise Architecture. Changes to the requirements baseline are administered by a Configuration Control Board (CCB) with the assistance of the Technical Control Board (TCB).

DARRTS tools are regularly updated as new versions are released or alternates are identified. Contractor tools for use on DARRTS will be provided as Government Furnished Property and currently include those items identified in Section 9, Attachment H.

2.4 OBJECTIVE

The Contractor shall provide all resources necessary to accomplish the deliverables described in this RFQ. The purpose of this TO is to acquire services necessary to execute critical modifications to the DARRTS environment to execute better data management and analysis in order to ensure business continuity. Performance standards and metrics for work performed under this TO will be evaluated employing the Quality Assurance Surveillance Plan (QASP). See Section 9, Attachment C.

2.5 TASKS

Task 1	Project Management and Reporting
Task 2	DARRTS DME Systems Development
Task 3	DARRTS BITM Pilot Tool and Licensing
Task 4	Task Order Transition

2.5.1 TASK 1 – PROJECT MANAGEMENT AND REPORTING

The contractor shall provide project management and reporting support under this TO. This includes the management and oversight of all activities performed by contractor personnel, including subcontractors, to satisfy the requirements identified in this TO. The contractor shall identify a Project Manager (PM) by name who shall provide management, direction, administration, quality control, and leadership of the execution of this TO.

2.5.1.1 SUBTASK 1 –PROVIDE PROJECT MANAGEMENT PLAN

Within ten days of award of this TO, the Contractor shall submit a draft DARRTS project management plan to the FEDSIM Contracting Officer Representative (COR) and the DARRTS Technical Point of Contact (TPOC) to document how the Contractor plans to execute and manage the tasks in this TO. The Government will make comments on the draft and the final PMP shall incorporate the Government's comments. The Project Management Plan shall describe all known project activities, milestones, resource estimates, funding requirements, assumptions, and risks. Specifically, the Project Management Plan will include at a minimum:

a. A narrative project scope statement
b. An updated DARRTS Work Breakdown Structure (WBS)
c. An updated Microsoft Project schedule aligning with the WBS
d. Project Budget baseline
e. Quality Management Plan
f. Risk Management and Risk Response Plan
g. Data Management Plan
h. Change Management Plan(s)
i. Change Request Log
j. Resource Plan
k. Communications Plan
l. Configuration Management Plan
m. Phase Exit Plan

2.5.1.2 SUBTASK 2 – PREPARE A WEEKLY STATUS REPORT

The Contractor will take part in weekly meetings with the TPOC. The contractor will provide a weekly status report electronically to the FEDSIM COR and the TPOC. Information to be addressed will include hours worked by task, status of the task, accomplishments, planned activities for the upcoming two weeks, and risk/issues and mitigation plans. Updated project schedules and any changes to the Project Plan will accompany status reports. At a minimum, the weekly status report will provide the following:

a. Activities during reporting period, by primary tasks located within each major enhancement (Include: On-going activities, new activities, activities completed; progress to date on all above-mentioned activities). Start each section with a brief description of the task

b. Problems and corrective actions taken. Include issues or concerns and proposed resolutions to address them
c. Prioritization and categorization of Program Change Requests (PCRs)
d. Personnel gains, losses and status
e. Government actions required
f. Updated schedule (Shows major tasks, milestones, and deliverables; planned and actual start and completion dates for each)
g. Any changes to the Project Management Plan
h. Accumulated invoiced cost for each CLIN up to the previous month
i. Projected costs

2.5.1.3 SUBTASK 3 – PREPARE A MONTHLY STATUS REPORT (MSR)

The Contractor shall develop and provide a Monthly Status Report (MSR) (Section 9 – List of Attachments, Attachment B) using Microsoft (MS) Office Suite applications, by the tenth of each month via electronic mail to the FDA TPOC and the FEDSIM COR. The MSR shall include the following:

a. Activities during reporting period, by task (Include: On-going activities, new activities, activities completed; progress to date on all above-mentioned activities). Each section shall start with a brief description of the task.
b. Problems and corrective actions taken, as well as issues or concerns and proposed resolutions to address them.
c. Personnel gains, losses and status
d. Government actions required
e. Schedule (Shows major tasks, milestones, and deliverables; planned and actual start and completion dates for each)
f. Any changes to the Project Management Plan
g. Accumulated invoiced cost for each CLIN up to the previous month.
h. Identify Bi-weekly burn rate and identify spikes greater than 5%, and identify any deviations that may impact the availability of funds over the life of the TO.
i. Projected cost of each CLIN for the current month and following months through the end of the TO
j. Risk analysis of current and potential spikes in activity and the impact to the funds remaining

As a part of Monthly reporting, the Contractor shall provide a Monthly Program Management Review (PMR) that describes important financial and status information to both the FDA TPOC and FEDSIM COR. The review shall be presented as a PowerPoint slide deck at a monthly PMR meeting, with content and meeting date agreed upon between the Contractor, FDA, and FEDSIM. Example topics from previous PMRs include the following:

a. A Financial Dashboard
b. Spending Patterns

c. Financial Details
d. Cost Metrics
e. Resource Management
f. Team Distribution
g. Major Milestones
h. Work Statistics (examples: Data Admins, Production Support Tickets, etc.)
i. Program Risks
j. Program Roadmaps

2.5.2 TASK 2 – DARRTS SYSTEMS MODIFICATION

2.5.2.1 SUBTASK 1 – DARRTS CHANGES

The following DARRTS modification activities are to be executed in this TO. All modifications will follow the FDA's standard development lifecycle processes and utilize the appropriate resources for each phase. If necessary, minor releases may be executed.

The main development work under this TO will occur in four areas. These include the following:

a. Generics structured data modifications
b. Regulatory Automation Tool (RAT) review modifications
c. New Drug structed data modifications
d. BITM Pilot data layer analysis tool and licensing

Generics Structured Data Modifications

The Contractor shall:

a. Create and implement a structured user interface for reviewers to streamline information and facilitate the drug product quality and drug facilities review.
b. Create and implement a system and data interface for regulatory and scientific data (Regulatory Review Data and reference UNII chemical structure)
c. Automate document template(s)
d. Enable capabilities to draw chemical structures
e. Provide Meta Data Management capabilities
f. Provide data analytics and knowledge management capabilities
g. Analyze the current process to define the standardization of functions across screens and workflow
    i. Office of Lifecyle Drug Products (OLDP), Office of Process and Facilities (OPF) and Office of New Drug Products (ONDP)-Biopharm require independent screens with variations that require consolidation/standardization of functions
    ii. Streamline the Primary, Secondary and Tertiary review processes
h. Determine requirements for integration of Regulatory Data from DARRTS and Office of Regulartory Affairs (ORA) databases

i. Map data structures and identify data elements necessary for compliance process
j. Define and develop Data Model
k. Identify Reference Data Management fields
l. Determine requirements for interfacing systems for both Inbound and Outbound interfaces (Electronic Document Room (EDR) / Global Summit on Regulatory Science (GSRS))
    i. Extensive pdf page search capabilities i.e. by text or page number
    ii. Ability to draw and store chemical structures
m. Analyze and Adopt document generation templates
n. Review and incorporate Business rules/ validations
o. Perform Data Migration from current pilot data store
p. Identify dashboard/reporting needs
q. Determine and develop training / user manual documentation
r. Create Framework to provide Pilot/ Prototype for Data Analytics and knowledge management
s. Perform infrastructure set up

Regulatory Automation Tool (RAT) Review Modifications

The Contractor shall:

a. Create a structured user interface for Regulatory Project Managers and Chief Project Manager Staff to facilitate the regulatory review process
b. Create a system and data interface for regulatory and meeting data
c. Provide automation of electronic communication capabilities such as e-mail
d. Automate and integrate Electronic Document Templates
e. Determine requirements for interfacing systems for both Inbound and Outbound interfaces
f. Provide search and reporting capabilities
g. Analyze the current process to define the standardization of functions across screens and workflow
h. Office specific including Office of Generic Drugs (OGD), Office of New Drugs (OND), Office of Pharmaceutical Quality (OPQ) and Office of Surveillance and Epidemiology (OSE)
i. Investigational New Drug (IND), New Drug Application (NDA), Biologices License Applications (BLA) Process, FDA/Industry meeting, Marketing application process, Safety Meeting reports, assignment features, meeting invites and Administrative enhancements
j. Map data structures and identify data elements necessary for compliance process
k. Define and develop Data Model

l. Identify Reference Data Management fields
m. Analyze and Adopt electronic document generation templates
n. Review and incorporate Business rules/ validations
o. Perform Data Migration as needed
p. Create user manual documentation/ training
q. Build a framework to support Data Analytics and knowledge management
r. Execute infrastructure set up

New Drug Data Modifications

The Contractor shall:

Develop a module with a structured user interface for new drug reviewers and project management staff to streamline information and facilitate pre/post-safety and new drug labeling reviews. In addition to allowing for the new drug process assessments, the module will provide users with an automated tool to log, track, manage, and report for specific safety signal, issues, new drug labeling and assessment reviews referenced in the application review process.

The Contractor shall:

a. Analyze the current process to define the standardization of functions across screens and workflow
b. Structure user interface for OND staff based on access privileges
c. Capture data from drug development application (IND, NDA) submissions
d. Enable data capture from documentation (e.g., protocol reviews, memos, requests to Sponsors for additional information, minutes of meetings) of reviews
e. Develop knowledge database
f. System and data interface for regulatory and scientific data (Regulatory Review Data and reference)
g. Automation of Document Template
h. Meta Data Management
i. Map data structures and identify data elements necessary for compliance process
j. Define and develop Data Model
k. Identify Reference Data Management fields
l. Determine requirements for interfacing systems for both Inbound and Outbound interfaces (many different)
m. Extensive pdf page search capabilities i.e. by text or page number
n. Linking to external links (publications etc.)
o. Analyze and Adopt document generation templates

p. Review and incorporate Business rules/ validations
q. Identify dashboard/reporting needs
r. Determine and Training / user manual documentation
s. Infrastructure set up

Prioritization of work will be determined through collaboration between the business and IT project teams with final approval provided by the DARRTS Technical Control Board (TCB), Change Control Board (CCB) and/or the FDA TPOC. As with other development work, the Contractor shall perform analysis, gather requirements, design, develop, test, migrate data, provide necessary support, and implement prioritized modifications.

2.5.2.2 SUBTASK 2 – REQUIREMENTS IDENTIFICATION

As a part of the DARRTS changes, the Contractor shall perform the activities described below related to developing requirements for the enhanced capabilities of DARRTS. This shall include the following:

a. Recommendations for updates to the Concept of Operations (CONOPS) that reflect an understanding of the FDA business requirements
b. Requirements gathering, analysis, and tracking of follow-up activities
c. DARRTS High Level Requirements document
d. DARRTS detailed System Requirements Specifications for new capabilities
e. DARRTS Traceability Matrix
f. Updates to the requirements archive with final requirements information
g. As needed the contractor shall perform/provide
    i. Use Case development
    ii. Story boards and process modeling for User Requirements Documents (URD)
    iii. User interface mockups
    iv. IT services in support of validating business processes

2.5.2.3 SUBTASK 3 – DEVELOPMENT OF APPROVED REQUIREMENTS

The Contractor shall develop DARRTS approved requirements with the objective of designing, developing, testing, integrating and implementing in accordance with the HHS Enterprise Performance Life Cycle (EPLC). The FDA TPOC or his delegates will review any recommendations from the Contractor for any changes to the FDA development, test, production, and training environments to consider for inclusion or amendment of the approved requirements.

The Contractor shall:

a. Participate in the FDA's EPLC processes and provide EPLC stage gate artifacts and lessons learned as required by the FDA's EPLC process
b. Provide suggestions for changes to technical descriptions for hardware and software necessary for Development, Test, Training, Pre-Production and Production environments.

The Government will provide the Development, Test Training, Pre-Production and Production environments as Government Furnished Property (GFP). Any additions and amendments to the software tools to be used in the FDA environment must be proposed and approved by the FDA TPOC and FEDSIM COR. Contractors should not use any unapproved product during any phase of lifecycle.

c. Support the activities of the DARRTS Change Control Board and the Technical Control Board and assist in the development, documentation and review of problem/change requests. As part of this deliverable, the Contractor shall within the limits of access provided by the FDA provide/perform:
    i. Provide Requirements, Development & Test representation for all change tickets being reviewed during the Pre-TCB/TCB/CCB meetings
    ii. Complete the necessary CCB Decision Forms and forward to OBI prior to the CCB meeting
d. Provide necessary support to the FDA for deploying software and migrating data into FDA environments. The Contractor shall justify any deviation from the FDA/OIM standard environments in the Contractor's PMP and obtain Government approval from the FDA TPOC and FEDSIM COR prior to initiation of migration activities. As part of this deliverable, the Contractor shall within the limits of access provided by the FDA provide/perform:
    i. Examination of the environments and validate that each meets the necessary requirements for the production tasks.
    ii. Support to the Government process to deploy software and migrate data into the Development, Test, Training, Pre-Production, and Production environments
    iii. Support to the Government to implement the capability to migrate software into the development, test, Pre-Production, Production, and training environments.
    iv. Reporting upon issue identification of any failure to implement these environments.
    v. Appropriate FDA/OIM escalation procedures if a situation blocking the progress of deliverables is not resolved
    vi. Post-implementation review
e. Provide changes to the documented data storage, data warehouse/repository, and access designs for the database layer, the designs of the user interface, and the designs of the business rules and the application logic represented in the approved requirements
f. As it relates to DARRTS, maintain a copy and provide suggested changes to the architecture or high-level design document that describes the system's top-level structure. This document will provide a top-level design for the interfaces external to the software system and between the software components of the software system. FDA expects the Contractor to maintain this document as changes are identified
g. Perform changes to the data model. The Contractor shall load data into the database to evaluate data load strategies and to provide test beds for software development
h. Design software modules capable of implementing required capabilities as specified in approved requirements and maintained under change control.
i. Code the software modules using techniques and tools, ensuring that developed code can be maintained by FDA approved toolsets

j. Revise and maintain under change control the existing DARRTS Test Plan.
k. Execute tests to ensure that DARRTS Releases will satisfy the requirements for the software product and including:
    i. Defined Test Scripts/Cases/Scenarios and properly prepared test data
    ii. Documented test cases and test results using the FDA/OIM test tools
    iii. Unit testing, integration testing, and system testing of all application code and associated database(s)
    iv. Prioritization and categorization of PCRs
    v. Creation of a Version Description Document prior to each software release
    vi. Functional testing, usability testing, performance testing, security testing, 508 compliance testing and regression testing
    vii. Record of all defects discovered during testing in the defect tracking system; correction of the defects; and re-testing
    viii. Track that the implementation of each software requirement is tested for compliance
    ix. Upon successful completion of all test and quality assessments, update and preparation of the deliverable software product for User Acceptance Testing (UAT)
    x. Performance of tests and other quality assessments (as determined in coordination with FDA PO) which ensure that:
        a) As-coded software products (such as a software item) reflect the approved requirements as maintained under change control
        b) The acceptance criteria and tests prescribed by the test plans are adequate for the acceptance of the software products
        c) Test data complies with the acceptance specification.
        d) Software products have been successfully tested and meet their specifications
        e) Test reports are correct and discrepancies between actual and expected results have been resolved
        f) All results have been documented in the System Test Report
        g) Section 508, Regression, and integration testing have been successfully carried out and documented
        h) Security testing is supported, consulted on, and performed security testing
        i) Support System Interface Testing is carried out
    xi. Update of the Implementation Plan as appropriate
    xii. Support and facilitation of user acceptance testing (UAT) of the application and associated database to also include, as necessary, Extended Testing (XT) with key government SMEs
l. Provide user documentation that complies with approved requirements.
m. Participate in necessary ISCP Security exercises and provide feedback documentation as required during each exercise
n. Provide any necessary masking data for Development, Test, and Pre-Production environments
o. Update the System Security Plan as appropriate
p. Consult, as necessary, in support of certification and accreditation activities

q. Update the Contingency and Disaster Recovery Document as appropriate
r. If necessary for each DARRTS release or any issue identified, provide support to the FDA or Data Centers to install and make DARRTS operational in each environment including the Production environment.
s. If necessary for each DARRTS release, provide support for data migration between systems and environments
t. Perform configuration management and quality control over all system development lifecycle activities utilizing industry best practices and FDA standards
u. Perform training activities as required including: Delivery of the training is the responsibility of the Government
    i. Enhance the existing DARRTS user manual with updated system features for each release.
    ii. Prepare materials for the training classes
    iii. Provide support, as required, for the instructor presentation materials, including, but not limited to, support of any training examples and establishment and refreshing of the training databases.
    iv. Update existing user guide
    v. Develop Quick Reference sheets
    vi. Prepare feedback instruments for trial sessions
    vii. Work with government staff to provide back up support during the scheduled training sessions. At the option of the FDA, a representative of the Contractor's staff should be on site in order to support any problems and to address any changes in the materials for subsequent training sessions
v. All system documentation shall be updated as of the most recent release (e.g., system architecture, user guides, release documentation, design documentation, run books).
w. All outstanding Change Requests shall be captured in the appropriate change management tool.
x. All source code for this task order currently owned by the FDA shall be updated in the appropriate version control tool including source code in test and development (e.g., database, application, services, web pages, and websites).
y. All regular maintenance activities shall be documented for all systems.
z. All current life cycle process documentation related to the systems shall be up to date.
aa. The Contractor shall respond to data calls and participate in transition meetings as requested by the Government
bb. The Contractor shall assist with documenting and returning all Government furnished equipment as directed by the COR and FDA Property Officer.
cc. The Contractor shall provide information about any changes to staffing to the FDA TPOC and FEDSIM COR

2.5.2.4 SUBTASK 4 – TESTING SUPPORT SERVICES

The Contractor shall execute DME quality control efforts and testing processes in accordance with the Department of Health and Human Services (HHS) EPLC. The Contractor shall

periodically recommend and provide test cases and updates to testing documentation, as well as attending audit meetings at the end of every quarter or after every major release. In addition, the Contractor shall:

a. Fully support EPLC testing processes including Stage Gates.
b. Create and maintain unit test cases and perform unit testing for reports that are scheduled for release. Perform security testing as part of the unit testing process.
c. Develop and test database scripts for deployment.
d. Create test cases and test data for testing purposes.
e. Develop Release Test Plans.
f. Review and maintain the Master Test Plan.
g. Develop System, User Acceptance Test (UAT) and Final Test Reports.

Specific areas of testing to be executed include the following:

a. Section 508 Compatibility Testing

i. Use the SSB BART Group Accessibility Management Platform (AMP) tool to verify that the new screens and reports are compliant with Section 508 based standards

b. Regression Testing

i. As part of the Regression testing effort, the contractor shall verify the following:
   a) The software has remained intact.
   b) Manual and Automation testing will be used to run tests that were created for the whole DARRTS system to make sure the tests still complete successfully.
   c) A baseline set of data and scripts are maintained and executed to verify that the functionality introduced during the release has not created errors in the existing production release.

ii. Any issues related to the functional, non-functional and User Interface found during the execution of the test cases will be recorded and tracked in JIRA. Retesting will be performed once the issues are resolved.

c. Final Performance Testing

i. Script Creation for the PI-4 and PI-5 Functionalities
ii. Performance Test will be executed for the whole DARRTS Application including all the major functionalities developed across all Increments
iii. Any Bottlenecks or performance issues identified will be resolved.
iv. Performance Testing Report

d. Test Stage Gate

i. Meeting with key stakeholders to review the Release 5.0 Test Analysis Report and discuss system testing.
ii. Make UAT-ready decision

e. Final UAT

i. User Acceptance Testing is performed in the Pre-Prod environment upon completion of the verification of the deployment. During this time, end users and members of the Office of Business Informatics (OBI) will test the application to make sure that the current functionality still works as expected. A release notes document, including defects fixed, change requirements included, and the work-around solutions for any outstanding issues, will be released to the DARRTS UAT team in the Implementation stage gate.

f. Implementation Stage Gate

i. Meeting with key stakeholders to review the Release 5.0 UAT findings and resolution.
ii. Make a go-live decision
iii. Complete the stage gate review checklist

2.5.2.5 SUBTASK 5 – RELEASE MANAGEMENT

The Contractor shall support Release Management processes including infrastructure support, deployment planning, deployment support, support for sandbox, development, test, training, preproduction, and production environments, issue management and resolution, and developing associated documentation. The Contractor shall use Apache Subversion (SVN) to maintain version control of releases.

In addition, the Contractor shall:

a. Participate in the FDA Release process and create Version Description Documents (VDDs) for all releases. The VDD shall include all code and installation instructions necessary for the installation of software on the Development, Test, Training, Pre-Production and Production environments.
b. Provide support for emergency releases.
c. The Contractor shall conduct configuration management in accordance with the Configuration Management Plan.
d. The Contractor shall practice version control of all critical project documents and application and database components, using versioning tools provided as GFP in Section J, Attachment H.

Specific areas of release management to be executed include the following:

a. Infrastructure support Pre-PROD and PROD

i. Submit Firewall requests for connections to other servers in PreProd and PROD
ii. Submit Load Balancer requests for F5 connections in PreProd and PROD
iii. Submit Change Requests for configuring Weblogic in PreProd/PROD environment
iv. Submit necessary documentation for configuring single sign on setup in PreProd/PROD environments.
v. Setup and configure Puppet deployment tool for PreProd and PROD
vi. Setup and configure AppDynamics tool for performance monitoring of DARRTS application in PreProd and PROD.

b. Deployment and Post-Deployment Support

i. Create VDD for 12c Weblogic installation and configuration in Production.
ii. Submit RFC and VDD for DARRTS deployment in production
iii. Submit RFC and VDD for UAC and Precedent Tracking deployment in production
iv. Work with Load Balancer team for DARRTS cutover from 10g to 12c including conversion from HTTP to HTTPs
v. Work with Infrastructure monitoring team (Solarwinds) to setup and monitor DARRTS system post go-live.
vi. Monitor and resolve DARRTS Application for Issues post go live related to either functional or infrastructure.

2.5.2.6 SUBTASK 6 – SERVICE LEVELS FOR DME SUPPORT SERVICES

All reports shall function according to the service level agreement of each primary system, e.g. Monday through Friday, from 07:00AM through 07:00PM ET, except at those times when the FDA performs maintenance that requires the system to be down.

The Contractor shall coordinate any scheduled downtime due to maintenance, including upgrades, with the TPOC.

The Contractor shall ensure that reports are functional within four business hours of the completion of any FDA scheduled maintenance.

The Contractor shall resolve all outstanding user requests and issues within the established resolution time for the corresponding severity level assigned to that particular trouble call by the OITSS Call Center or FDA TPOC.

2.5.3 TASK 3 –BITM PILOT DATA ANALYSIS TOOL AND LICENSING

The software will be implemented as a part of the DARRTS Precedents module for OND/ Office of Hematology and Oncology Products (OHOP) and Oncology Center of Excellence (OCE) Cancer Clinical Trials and OPQ, OGD review, and connected to data sources such as regulatory decisions from DARRTS, to allow better review and understanding of the data. This will allow users to view meta data, aggregate information, and look at endpoints across the data to correlate and harmonize information, as well as ask statistically sophisticated questions of the data.

The Contractor shall:

a. Procure 160 term software licenses for the BITM Pilot. Term licenses for the BITM Pilot shall include configuration, support, and maintenance.

b. Enable a granular access-control framework.
    i. Configure access controls to enable administrators to create user groups, set and adjust data and application access permissions and integrate access control with the FDA's user management system.

c. Platform data integration and configuration
    a. Integrate clinical trials data from the EDR system via a direct connection with EDR
        1. Initial integration will focus on the past ten years of applications.
    b. Where possible integrate regulatory actions to enrich the view of structured clinical trial submissions.
    c. Enrich the data views with applicable external data sources (e.g. Project Data Sphere).
    d. Configure user search and filtering interfaces for clinical trial discoverability to retrieve relevant trials for a given research or regulatory question
    e. Train users on software tools to create additional views of integrated data as needed.

d. Configure Clinical Trials Executive Dashboard
    i. Configure a dashboard interface to perform filters and overviews of oncology clinical trials at the FDA.
        a) Include: top-down view of trials, trial design, demographics, adverse events, drug information, and other key facets.
        b) Provide a high-level overview of clinical trial assets as raw ingredients for a cross-trial analysis with clinical officer validated metadata regarding those trials

c) Provide the ability to view key variables easily, including demographics information within a dynamically defined trial cohort through multiple visualizations including geospatial visualizations on maps
d) Provide aggregation of adverse event signals across trials to allow for safety detection analysis across select trials

e. Configure Regulatory Policy Outcomes
   i. Configure interfaces that surface data quality gaps across submissions
      a) Examples include the most common domains and variables submitted by sponsors, repeated "unique" IDs, non-standard submission formats, and other data issues impacting efficacy of review.
      b) Configure for safety views that allow medical officers to view the longitudinal aspects of safety signals in reference to Cancer Clinical Trails.
      c) Provide for support of methods to expose and export analysis for wider distribution. Examples include exporting of figures for publication or web consumption, and export of datasets.

f. Enable Advanced Research
   i. Enable ability for medical officers to build their own cross-trial analysis datasets .
   ii. Enable ability for medical officers and other subject matter experts to clean, harmonize, and structure their own data according to their own definitions. Examples include the ability to change how column headers in domains should be mapped to a concept, or how various adverse event terms or demographic selections should be considered the same group.
   iii. Integrate structured variable definition documents, such as define.xml, into software tools to guide harmonization choices
   iv. Configure frameworks to templatize the most common analytic paths
   v. Configure interface to enable medical officers to collaborate on prior harmonization work, and avoid duplicative efforts while tracking provenance.

g. Other Data Integration and configuration
   i. Integrate unstructured PDFs, such as trial protocols
   ii. Configure tools for the following:
      a) Data Extraction and Entry
         1. Table extraction – enable the ability to copy tables from PDF submissions and extract the content of the table so that it can be stored and manipulated in a structured or semi-structured format.
         2. Streamline structured extraction to semi-automatically extract from common submission formats, landing the data in a form that can be fully comparable through the history of submissions. For those in which no table is extracted due to an unanticipated format, flag the document for manual extraction or an adaptation of identification logic.

3. Enable the creation of entry forms and help for structured and unstructured fields.

b) Knowledge Management and Data Validation
   1. Configure tools to provide reviewers with interfaces to validate and correct semi-automated extractions.
   2. Enable tracking and organizing of metadata associated with a given entity
   3. configure a data cleanliness issue tracking system that allows commenting and discussion on data, with direct cross-references to the underlying source of the data.

c) Cross-Submission Comparison Analysis
   1. Enable comparisons of structured and semi-structured information between applications such as: (1) Proportions of active and inactive drug ingredients in the formulation, (2) Specifications, (3) Container closures and labelling, (4) Pharmacokinetics and pharmacodynamics in bioequivalence.
   2. Enable data search and filtering to determine whether a particular aspect of the application under review is unique within that drug or across drugs.
   3. Enable tagging in order to bring structure to unstructured sources.

h. Provide support and training
   i. Provide training and support for software tools
      a) Support may include:
         1. General platform user guides for common tools and workflows
         2. Data and domain-specific documentation
         3. Group user training to onboard new users and teach advanced platform skills to experienced users
         4. Individual deskside support for advanced usage
         5. One-on-one platform management, data integration, and platform integration training and documentation for technical users
         6. Remote assistance over phone or electronic channels

2.5.4 TASK 4 – TRANSITION-OUT

To ensure a smooth transition from this TO to the subsequent TO, the Contractor shall be the lead on the transition activities during the transition period. The Contractor shall perform work including the activities listed below. The Contractor shall complete, validate, and report status of these activities to the FDA TPOC and FEDSIM COR on a weekly basis during the transition out period.

The Contractor shall submit to the FDA TPOC and FEDSIM COR, for approval, a detailed Transition Plan 60 days prior to TO completion. The plan shall identify tasks, deliverables and

milestones to ensure an orderly and complete transition. At a minimum, the Transition Plan shall include:

a. Roles and responsibilities for Contractor staff during the transition, including the identification of a transition lead
b. The schedule and milestones for completing the transition;
c. Process for progress reviews, identifying problems, and ensuring prompt problem resolution
d. Methodologies for conducting and ensuring a seamless transition
e. Activities to instruct the successor Contractor on all current life cycle processes involving the systems (e.g., deployments, configuration management, etc.)

Orderly transfer of all historical information, system documentation, and DARRTS Program source code to the successor Contractor

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4.1 PLACE OF INSPECTION AND ACCEPTANCE

4.1 PLACE OF INSPECTION AND ACCEPTANCE

Inspection and acceptance of all work performance, reports, and other deliverables under this TO shall be performed by the FDA TPOC at:

6003 Executive Boulevard, Suite 400
Rockville, MD 20852

Or

3WFN
11601 Landsdown Street
North Bethesda, MD 20852

The FEDSIM COR shall perform acceptance at:

GSA FEDSIM
1800 F Street NW
Suite 3100
Washington, DC 20405

4.2 SCOPE OF INSPECTION

All deliverables will be inspected for content, completeness, accuracy, and conformance to TO requirements by the FDA TPOC and FEDSIM COR. Inspection may include validation of information or software through the use of automated tools, testing, or inspections of the deliverables, as specified in the TO. The scope and nature of this inspection will be sufficiently comprehensive to ensure the completeness, quality, and adequacy of all deliverables.

The Government requires a period NTE 15 workdays after receipt of final deliverable items for inspection and acceptance or rejection.

4.3 BASIS OF ACCEPTANCE

The basis for acceptance shall be compliance with the requirements set forth in the TO and relevant terms and conditions of the contract. Deliverable items rejected shall be corrected in accordance with the applicable clauses.

Reports, documents, and narrative-type deliverables will be accepted when all discrepancies, errors, or other deficiencies identified in writing by the Government have been corrected. If the draft deliverable is adequate, the Government may accept the draft and provide comments for incorporation into the final version.

All of the Government's comments on deliverables must either be incorporated in the succeeding version of the deliverable, or the contractor must demonstrate to the Government's satisfaction why such comments should not be incorporated.

If the Government finds that a draft or final deliverable contains spelling errors, grammatical errors, or improper format, or otherwise does not conform to the requirements stated within this TO, the document may be immediately rejected without further review and returned to the contractor for correction and resubmission. If the contractor requires additional Government guidance to produce an acceptable draft, the contractor shall arrange a meeting with the FEDSIM COR.

4.3.1 For IT development, the final acceptance will occur when all discrepancies, errors, or other deficiencies identified in writing by the Government have been resolved, through documentation updates, program correction, or other mutually agreeable methods.

4.4 DRAFT DELIVERABLES

The Government will provide written acceptance, comments, and/or change requests, if any, within 15 workdays from Government receipt of the draft deliverable.

Upon receipt of the Government comments, the contractor shall have ten workdays to incorporate the Government's comments and/or change requests and to resubmit the deliverable in its final form.

4.5 WRITTEN ACCEPTANCE/REJECTION BY THE GOVERNMENT

The FDA TPOC or FEDSIM COR will provide written notification of acceptance or rejection of all final deliverables within 15 workdays. All notifications of rejection will be accompanied with an explanation of the specific deficiencies causing the rejection.

4.6 NON-CONFORMING PRODUCTS OR SERVICES

Non-conforming products or services will be rejected. Deficiencies will be corrected by the contractor within ten workdays of the rejection notice. If the deficiencies cannot be corrected within ten workdays, the contractor shall immediately notify the FEDSIM COR of the reason for the delay and provide a proposed corrective action plan within ten workdays.

If the contractor does not provide products or services that conform to the requirements of this TO, the Government will not pay the fixed price associated with the non-conforming products or services.

5.1 PERIOD OF PERFORMANCE

The period of performance for this TO is 12 months from date of TO award .

5.2 PLACE OF PERFORMANCE

Place of performance is primarily at the FDA offices at 11601 Landsdown Street, North Bethesda, Maryland during normal business hours (7:00 a.m. – 5:00 p.m.), Monday-Friday, excluding Federal holidays. Operational hours and days may vary. However, in the process of completing tasks outlined in this TO, work may require the Contractor to move program staff to an FDA approved alternate primary work site or travel between work sites. The Contractor will require travel between the following locations:

a. White Oak (10903 New Hampshire Avenue, Silver Spring, Maryland)
b. FDA OIM facilities on Landsdown Street, North Bethesda, Maryland
c. 6003 Executive Blvd in Rockville, Maryland
d. Other FDA identified alternate work locations in the Washington, DC metropolitan area as needed.

No long distance travel is anticipated to be required in support of this effort.

All designated key personnel will be required to work onsite at FDA offices listed above.

5.3 TASK ORDER SCHEDULE AND MILESTONE DATES

The following schedule of milestones will be used by the FEDSIM COR to monitor timely progress under this TO.

The following abbreviations are used in this schedule:

DEL: Deliverable
IAW: In Accordance With
NLT: No Later Than
TOA: Task Order Award
All references to Days: Government Workdays

Deliverables are due the next Government workday if the due date falls on a holiday or weekend.

Data Rights Clause* - Abbreviations in this column of the table below shall be interpreted as follows:

UR: Unlimited Rights, per FAR 27.404-1(a) and 52.227-14
RS: Restricted Software, per FAR 27.404-2 and 52.227-14
LD: Limited Rights Data, per FAR 27.404-2 and 52.227-14
SW: Special Works, per FAR 27.405-1 and 52.227-17

For software or documents that may be either proprietary COTS or custom, RS/LD rights apply to proprietary COTS software or documents and UR rights apply to custom software or documents. The Government asserts UR rights to open source COTS software. Any collateral

agreements (within the meaning of FAR 52.227-14) proposed for data, regardless of the type of rights offered, shall be subject to the requirements of RFQ Section 7.8. For purposes of the foregoing, the terms "collateral agreement," "Supplier Agreement," and "Commercial Supplier Agreement" have the same meaning.

The contractor may request and the Government may grant different or more restrictive rights, such as SW rights, than are depicted in the following table. The Government does not assert any rights to management software tools if the contractor does not plan to charge the Government directly for that tool and does not propose that the Government will own or use that tool.

The contractor shall deliver the deliverables listed in the following table:

5.3.1 DARRTS PROJECT MANAGEMENT

DEL. #	MILESTONE/ DELIVERABLE	CLIN	RFQ REFERENCE	DATE COMPLETION/DELIVERY	GOV'T RIGHTS
	Project Start Date			Date of Task Order Award	NA
01	Project Management Plan	0001	2.5.1.1		UR
02	PMP Draft (Revised)	0001	2.5.1.1	10 days after TOA	UR
03	PMP Final, updated thereafter	0001	2.5.1.1	30 days after TOA	UR
04	PMP Revised	0001	2.5.1.1	As Required	UR
05	Weekly Status Report / Meeting	0001	2.5.1.2	Weekly	NA
06	PCR Status Report	0001	2.5.1.2	Weekly	UR
07	Monthly Status Report	0001	2.5.1.3	Monthly (10th calendar day of the next month)	NA
08	Final Task Order Report	0001	2.5.1.4	30 days prior to TO completion	UR
09	Problem Notification Report	0002	5.7	Within 1 day of problem discovery	NA

5.3.2 DARRTS DME ENHANCEMENTS

DEL #	MILESTONE/ DELIVERABLE	CLIN	RFQ REFERENCE	DATE COMPLETION/DELIVERY	GOV'T RIGHTS
10	Review and provide input to the DARRTS Concept of Operations (CONOPS)	0002	2.5.2.2	Updated Quarterly, as Needed	UR
11	Updated Requirements work plan	0002	2.5.2.2	15 days after TOA; Updated Regularly but No Less than Quarterly to include a midcourse and final review	UR
12	Updated DARRTS Traceability Matrix	0002	2.5.2.2	Updated Regularly but No Less than Quarterly to include a midcourse and final review	UR
13	Updated DARRTS Requirements Documents	0002	2.5.2.2	Updated Regularly but No Less than Quarterly to include a midcourse and final review	UR
14	Story Boards and process modeling for URDs	0002	2.5.2.2	Within 15 days of URD acceptance	UR
15	DARRTS Detailed System Requirements Specifications	0002	2.5.2.2	Draft one month after TOA; Updated Regularly but No Less than Quarterly to include a midcourse and final review	UR
16	Update Requirements Archive	0002	2.5.2.2	Updated Regularly but No Less than Quarterly	UR
17	Documented software module designs	0002	2.5.2.3	Updated Regularly but No Less than Quarterly	UR
18	Software Releases	0002	2.5.2.3	Release schedule determined by the FDA TPOC and FEDSIM COR	UR

DEL #	MILESTONE/ DELIVERABLE	CLIN	RFQ REFERENCE	DATE COMPLETION/DELIVERY	GOV'T RIGHTS
19	Implementation Plans	0002	2.5.2.3	Updated Regularly but No Less than Quarterly	UR
20	Post implementation Review	0002	2.5.2.3	Within 1 week after implementation	UR
21	Update System Design Document	0002	2.5.2.3	Updated Regularly but No Less than Quarterly	UR
22	Changes Documented in Data Storage and Access Design	0002	2.5.2.3	Updated Regularly but No Less than Quarterly	UR
23	Changes Documented in Architecture or High-Level	0002	2.5.2.3	Updated Regularly but No Less than Quarterly	UR
24	EPLC Stage Gate documentation and Lessons learned	0002	2.5.2.3	Per stage gate schedule	UR
25	Changes Documented to Valid Data Model and data dictionary	0002	2.5.2.3	Updated Regularly but No Less than Quarterly	UR
26	Software modules/code	0002	2.5.2.3	Updated Regularly but No Less than Quarterly	UR
27	Update DARRTS Test Plans	0002	2.5.2.3	Updated Regularly but No Less than Quarterly	UR
28	Version Description Documents	0002	2.5.2.5	1 week prior to software release	UR
29	Test Scripts/Cases/Scenarios	0002	2.5.2.3	Prior to system testing activities per software release	UR
30	Test Results/Reports	0002	2.5.2.4	At completion of system testing activities per software release	UR

DEL #	MILESTONE/ DELIVERABLE	CLIN	RFQ REFERENCE	DATE COMPLETION/DELIVERY	GOV'T RIGHTS
31	Defect Reports	0002	2.5.2.3	As agreed to by FDA TPOC and FEDSIM COR	UR
32	Review and provide input to System Security Plan	0002	2.5.2.3	Updated Regularly but No Less than Annually	UR
33	Review and provide input to Contingency and Disaster Recovery Document	0002	2.5.2.3	Updated Regularly but No Less than Annually	UR
34	User Documentation	0002	2.5.2.3	Updated as approved new functionality is delivered	UR
35	Training documentation/materials	0002	2.5.2.3	Updated as approved new functionality is delivered	UR
36	User Guide	0002	2.5.2.3	Updated as approved new functionality is delivered	UR
37	Quick Reference Sheets	0002	2.5.2.3	Updated as approved new functionality is delivered	UR
38	DARRTS Hardware/Software Upgrade Plans	0002	2.5.2.3	As agreed to by the FDA TPOC and FEDSIM COR	UR
39	Task Order Transition Plan	0002	2.5.4	Within 60 days of TO end date	UR
40	Public Release of Contract Documents	0002	5.3.3	Within 10 days of TOA	UR

The contractor shall mark all deliverables listed in the above table to indicate authorship by contractor (i.e., non-Government) personnel; provided, however, that no deliverable shall contain any proprietary markings inconsistent with the Government's data rights set forth in this TO. The Government reserves the right to treat non-confirming markings in accordance with subparagraphs (e) and (f) of the FAR clause at 52.227-14.

5.4 PUBLIC RELEASE OF CONTRACT DOCUMENTS REQUIREMENT

The contractor agrees to submit, within ten workdays from the date of the FEDSIM CO's execution of the initial TO, or any modification to the TO (exclusive of Saturdays, Sundays, and Federal holidays), a portable document format (PDF) file of the fully executed document with all proposed necessary redactions, including redactions of any trade secrets or any commercial or financial information that it believes to be privileged or confidential business information, for the purpose of public disclosure at the sole discretion of GSA. The contractor agrees to provide a detailed written statement specifying the basis for each of its proposed redactions, including the applicable exemption under the Freedom of Information Act (FOIA), 5 United States Code (U.S.C.) § 552, and, in the case of FOIA Exemption 4, 5 U.S.C. § 552(b)(4), shall explain why the information is considered to be a trade secret or commercial or financial information that is privileged or confidential. Information provided by the contractor in response to the contract requirement may itself be subject to disclosure under the FOIA. Submission of the proposed redactions constitutes concurrence of release under FOIA.

GSA will carefully consider the contractor's proposed redactions and associated grounds for nondisclosure prior to making a final determination as to what information in such executed documents may be properly withheld.

5.5 DELIVERABLES MEDIA

The contractor shall deliver all electronic versions by email and removable electronic media, as well as placing in the FDA's designated repository. The following are the required electronic formats, whose versions must be compatible with the latest, commonly available version on the market.

- Text MS Word
- Spreadsheets MS Excel
- Briefings MS PowerPoint
- Drawings MS Visio
- Schedules MS Project

5.6 PLACE(S) OF DELIVERY

Unclassified deliverables or correspondence shall be delivered to the FEDSIM CO or COR at the following address:

GSA FEDSIM
ATTN: Angela Collum, COR
1800 F Street NW
Suite G300 – QF0B
Washington, DC 20405
Email: angela.collum@gsa.gov

Copies of all deliverables shall also be delivered to the FDA TPOC at the following address:

FDA Office of Information Management and Technology (OIMT)
Michael T. Phillips
3WFN
11601 Landsdown Street
North Bethesda, MD 20852
Telephone: 301-796-7848
Email: Michael.Phillips@fda.hhs.gov

5.7 NOTICE REGARDING LATE DELIVERY/ PROBLEM NOTIFICATION REPORT (PNR)

The contractor shall notify the FEDSIM COR via a Problem Notification Report (PNR) (Section 9 – List of Attachments, Attachment D) as soon as it becomes apparent to the contractor that a scheduled delivery will be late. The contractor shall include in the PNR the rationale for late delivery, the expected date for the delivery, and the project impact of the late delivery. The FEDSIM COR will review the new schedule and provide guidance to the contractor. Such notification in no way limits any Government contractual rights or remedies including, but not limited to, termination.

6.1 CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The FEDSIM CO appointed a FEDSIM COR in writing through a COR Appointment Letter (Section 9 – List of Attachments, Attachment G). The FEDSIM COR will receive, for the Government, all work called for by the TO and will represent the FEDSIM CO in the technical phases of the work. The FEDSIM COR will provide no supervisory or instructional assistance to contractor personnel.

The FEDSIM COR and the FDA TPOC are not authorized to change any of the terms and conditions, scope, schedule, and price of the Contract or the TO. Changes in the scope of work will be made only by the FEDSIM CO by properly executed modifications to the Contract or the TO.

6.1.1 CONTRACT ADMINISTRATION

Contracting Officer:

Matthew Healey
GSA FEDSIM
1800 F Street, NW
Washington, D.C. 20405
Telephone: 202-357-5817
Email: matthew.healey@gsa.gov

Contracting Officer's Representative:

Angela Collum
GSA FEDSIM
1800 F Street, NW
Washington, D.C. 20405
Telephone: (770) 362-5755
Email: angela.collum@gsa.gov

Technical Point of Contact:

FDA Office of Information Management and Technology (OIMT)
Michael T. Phillips
3WFN
11601 Landsdown Street
North Bethesda, MD 20852
Telephone: 301-796-7848
Email: Michael.Phillips@fda.hhs.gov

6.2 INVOICE SUBMISSION

The contractor shall submit Requests for Payments in accordance with the format contained in General Services Administration Acquisition Manual (GSAM) 552.232-25, PROMPT

PAYMENT (NOV 2009), to be considered proper for payment. In addition, the following data elements shall be included on each invoice.

Task Order Number: *(from GSA Form 300, Block 2)*

Paying Number: *(ACT/DAC NO.) (From GSA Form 300, Block 4)*

FEDSIM Project Number: 29021HHM

Project Title: Document Archiving Reporting and Regulatory Tracking System (DARRTS) Data Management and Analysis Modifications, Task Order 29

The contractor shall certify with a signed and dated statement that the invoice is correct and proper for payment.

The contractor shall provide invoice backup data in accordance with the contract type, including detail such as labor categories, rates, and quantities of labor hours per labor category.

The contractor shall submit invoices as follows:

The contractor shall utilize FEDSIM's electronic Assisted Services Shared Information SysTem (ASSIST) to submit invoices. The contractor shall manually enter CLIN charges into TOS in the ASSIST Portal. Summary charges on invoices shall match the charges listed in TOS for all CLINs. The contractor shall submit invoices electronically by logging onto the following link (requires Internet Explorer to access the link):

https://portal.fas.gsa.gov

Log in using your assigned ID and password, navigate to the order against which you want to invoice, click the Invoices and Acceptance Reports link in the left navigator, and then click the *Create New Invoice* button. The AASBS Help Desk should be contacted for support at 877-472-4877 (toll free) or by email at AASBS.helpdesk@gsa.gov. By utilizing this method, no paper copy of the invoice shall be submitted to GSA FEDSIM or the GSA Finance Center. However, the FEDSIM COR may require the contractor to submit a written "hardcopy" invoice with the client's certification prior to invoice payment. A paper copy of the invoice is required for a credit.

6.3 INVOICE REQUIREMENTS

The contractor shall submit a draft or advance copy of an invoice to the FEDSIM COR and the FDA TPOC for review prior to its submission to GSA.

The final invoice is desired to be submitted within six months of project completion.

The contractor may invoice monthly on the basis of cost incurred for the LH CLINs. The invoice shall include the period of performance covered by the invoice and the CLIN number and title. All hours and costs shall be reported by CLIN element (as shown in Section 1 – Supplies or Services and Price/Costs), by contractor employee, and shall be provided for the current billing month and in total from project inception to date. The contractor shall provide the invoice data in spreadsheet form with the following detailed information. The listing shall include separate columns and totals for the current invoice period and the project to date.

a. Employee name (current and past employees)
b. Employee company labor category

c. Employee labor category
d. Monthly and total cumulative hours worked
e. Corresponding hourly rate
f. Cost incurred not billed

6.3.1 FIRM-FIXED-PRICE (FFP) CLINs

The contractor may invoice as stated in Section 1 – Supplies or Services and Prices for the FFP CLINs. The invoice shall include the period of performance covered by the invoice (all current charges shall be within the active period of performance) and the CLIN number and title. All prices shall be reported by CLIN element (as shown in Section 1 – Supplies or Services and Prices) and shall be provided for the current invoice and in total from project inception to date. The contractor shall provide the invoice data in spreadsheet form with the following detailed information. The listing shall include separate columns and totals for the current invoice period and the project to date.

a. FFP period of performance – as stated in Section 1 – Supplies or Services and Prices)
b. Total Amount Paid (Lump Sum) by CLIN

7.0 KEY PERSONNEL

7.1 KEY PERSONNEL

The following are the minimum personnel who shall be designated as "Key." The Government does not intend to dictate the composition of the ideal team to perform this TO. Therefore, the Government encourages and will evaluate additional Key Personnel as proposed by the offeror.

a. Technical Project Manager (PM)

The Government desires that Key Personnel be assigned for the duration of the TO. Key Personnel may be replaced or removed subject to Section 7 - Special Contract Requirements, Key Personnel Substitution.

7.1.1 TECHNICAL PROJECT MANAGER

It is desired that the PM has the following qualifications:

a. Experience in providing operations and maintenance support projects, specifically database support and enhancement projects
b. Experience managing customer relationships, project management and reporting, resource management and effective problem resolution skills
c. Experience with systems development Task Order within the FDA OIM or similar environment (desired)

7.1.2 KEY PERSONNEL SUBSTITUTION

The contractor shall not replace any personnel designated as Key Personnel without the written concurrence of the CO. Prior to utilizing other than personnel specified in proposals in response to a TOR, the contractor shall notify the Government CO and the COR of the existing TO. This notification shall be no later than ten calendar days in advance of any proposed substitution and shall include justification (including resume(s) and labor category of proposed substitution(s)) in sufficient detail to permit evaluation of the impact on TO performance.

Substitute personnel qualifications shall be equal to, or greater than, those of the personnel being substituted. If the Government CO and the COR determine that a proposed substitute personnel is unacceptable, or that the reduction of effort would be so substantial as to impair the successful performance of the work under the TO, the contractor may be subject to default action as prescribed by FAR 52.249-8, Default (Fixed-Price Supply and Service).

7.2 GOVERNMENT-FURNISHED PROPERTY (GFP)

The GFP is listed in Section 9 – List of Attachments, Attachment H. The Government will provide ID badges, workstations, and network access (to include printers) for Contractor personnel. GFP will be provided at Task Order Award.

7.2.1 GOVERNMENT-FURNISHED INFORMATION (GFI)

All existing DARRTS technical and management documents created under separate Task Orders are provided as Government Furnished Information at TO award.

7.3 SECURITY REQUIREMENTS

7.3.1 BACKGROUND

In accordance with FDA 1335 Personnel Security Clearance Requirements, the Office of the Assistant Secretary for Management and Budget, Department of Health and Human Services (DHHS), requires that DHHS employees and Contractor employees (including sub-Contractors) who will be working in a DHHS-owned or leased space and/or who will have access to DHHS equipment, and non-public privileged, proprietary, or trade secret information, undergo a background investigation of some type.

Contractor employees who will be in DHHS-owned or lease space for less than thirty (30) days are exempted from the background investigation requirement. These Contractor employees must be escorted at all time while in DHHS-owned or leased space.

7.3.2 GENERAL

Notwithstanding other submission requirements stated elsewhere in this Task Order, the Contractor shall submit the following information to the Contracting Officer, ten (10) calendar days prior to commencement of work hereunder:

a. Certification that all required security form packets and a list of Contractor employees names for whom the requisite security information has been provided to Division of Security Operations, Policy and Planning, Personnel Security Staff.

b. "Contractor's Commitment to Protect Non-public Information Agreement" forms signed by each employee named in paragraph a above.

With the exception of costs associated with fingerprinting Contractor employees outside of the FDA Personnel Security Office, the Government will conduct all required background investigations at no cost to the Contractor. The cost of fingerprinting Contractor employees at any location other than the FDA Personnel Security Office will be borne by the Contractor.

Contractor employees shall obtain security badges in order to access to DHHS-owned or leased property without an escort. (See 7.3.3 for details on the badging process). However, in the event that work must commence before security badges can be issued, Contractor employees will be allowed onto DHHS-owned or leased property, but must be escorted at all times.

The position risk levels for this Task Order are Public Trust Positions.

There are two potential position risk levels, which are:

a. Non-Sensitive Positions - Positions which involve the lowest degree of adverse impact on the efficiency of the Agency. The impact involving the duties is of limited effect. Contractor employees assigned to Level 1 who receive a security badge will be required

to provide additional security information for a background investigation as specified by information provided by the FDA TPOC.

b. Public Trust Positions - Positions in which the incumbent's actions or inaction could diminish public confidence in the integrity, efficiency, or effectiveness of assigned Government activities, whether or not actual damage occurs. Contractor employees must receive security badge as well as a background investigation.

7.3.3 BADGING PROCESS

The FDA TPOC will sponsor Contractor employees on the FDA Form 3391 for the purpose of obtaining an FDA Security Access Card. In order to obtain one, a Contractor employee must receive a "favorable" fingerprint return. Fingerprints must be submitted to the Personnel Security Office at least ten days prior to the commencement of work. Fingerprints will be submitted in one of two ways, depending on where the Task Order will be performed:

a. Contractor employees who will work in the Washington D.C. metro area will, at the direction of the FDA TPOC or his/her designee, contact the Personnel Security Branch to schedule a fingerprinting appointment, or

b. Contractor employees who will work in a field office will submit fingerprints to:
FDA Badging Office
10903 New Hampshire Avenue
Building 1, Room 1201
Silver Spring, MD 20993

An individual who receives an unfavorable report may, upon written request to Personnel Security Staff, obtain a copy of the report.

Upon the receipt of a "favorable" fingerprint return, each Contractor employee must present an original photo identification document in order to receive his/her badge. Acceptable forms of photo identification are referenced on the FDA Form 3391. Acceptable forms of secondary identification are listed on the back of the I-9 Form. This form can be obtained at http://uscis.gov/graphics/formsfee/forms/files/i-9.pdf.

7.3.4 INFORMATION ASSURANCE

The contractor may have access to sensitive (to include privileged and confidential) data, information, and materials of the U.S. Government. These printed and electronic documents are for internal use only and remain the sole property of the U.S. Government. Some of these materials are protected by the Privacy Act of 1974 (AMENDED) and Title 38. Unauthorized disclosure of Privacy Act or Title 38 covered materials is a criminal offense.

7.3.5 SECURITY CLEARANCES

The Government shall conduct an additional background investigation for individuals serving under this Task Order.

Required background investigations may include, but not be limited to:

a. Review of prior Government/military personnel records;
b. Review of FBI records and fingerprint files;
c. Searches of credit bureaus;
d. Personal interviews; and
e. Written inquiries covering the subject's background.

Background investigations will be conducted by the Office of Personnel Management (OPM).

The Contractor is responsible for ensuring that the integrity of Task Order performance is maintained pending completion of all appropriate background investigations of Contractor employees.

The Contractor shall require all TO employees to submit the appropriate forms for the appropriate risk level specified. The Contractor shall review all forms for completeness and accuracy prior to submitting them to the FDA. In addition to the submission of the required forms, the Contractor shall provide a cover letter which includes: Contractor's name, Task Order number, Contractor employee names, social security numbers, employee dates of birth, former names and name of Contracting Officer. All completed forms shall be transmitted, in a separate sealed envelope marked, "TO BE OPENED BY ADDRESSEE ONLY," to:

Food and Drug Administration
Office of Security Operations
Personnel Security Branch
10903 New Hampshire Avenue
Building 1, Suite 1201
Silver Spring, MD 20993

The Contractor shall send a separate letter to the Contracting Officer that includes the Task Order number and employee names.

The Contractor shall advise its prospective employees that all standard forms submitted to the FDA will be forwarded to the Office of Personnel Management (OPM) for scheduling background investigations.

Personnel Security Staff will resolve with the Contractor employee any issues arising out of inaccurate or incomplete forms.

Employees who have been previously granted a Government security clearance shall advise Personnel Security Staff of the details of such clearances to determine if a previous clearance level is suitable for the current FDA position.

At any time, if a Contractor employee for whom security forms have been submitted is terminated or otherwise ceases work under the Task Order, the Contractor shall immediately notify Personnel Security Staff, in writing, with copies to the respective FDA Project and Contracting Officers.

The OPM background investigation will take approximately 120 days. The Contracting Officer will notify the Contractor in writing if an employee is denied a clearance. Those individuals who have been cleared by Personnel Security Staff may continue to work under the BPA/TO. Those who are not cleared must cease work on the Task Order immediately.

If a Contractor employee changes job responsibilities under this Task Order, the Contractor shall notify the Contracting Officer, and the Government will make a determination whether an additional security clearance is required.

In the event that a cleared individual is replaced, the Contractor shall notify the Contracting Officer and comply with all requirements of this clause, as specified herein, prior to the commencement of work by the replacement individual.

The Contractor shall be responsible for the return of any Government issued security badges to the FDA TPOC.

7.4 ORGANIZATIONAL CONFLICT OF INTEREST AND NON-DISCLOSURE REQUIREMENTS

7.4.1 ORGANIZATIONAL CONFLICT OF INTEREST (OCI)

a. If a contractor has performed, is currently performing work, or anticipates performing work that creates or represents an actual or potential OCI, the contractor shall immediately disclose this actual or potential OCI to the FEDSIM CO in accordance with FAR Subpart 9.5. The nature of the OCI may involve the prime contractor, subcontractors of any tier, or teaming partners.
b. The contractor is required to complete and sign an OCI Statement (Section 9 – List of Attachments, Attachment J). The contractor must represent either that (1) It is not aware of any facts which create any actual or potential OCI relating to the award of this contract, or (2) It has included information in its quote, providing all current information bearing on the existence of any actual or potential OCI and has included a mitigation plan in accordance with paragraph (c) below.
c. If the contractor with an actual or potential OCI believes the conflict can be avoided, neutralized, or mitigated, the contractor shall submit a mitigation plan to the Government for review.

d. In addition to the mitigation plan, the FEDSIM CO may require further information from the contractor. The FEDSIM CO will use all information submitted by the contractor, and any other relevant information known to GSA, to determine whether an award to the contractor may take place, and whether the mitigation plan adequately avoids, neutralizes, or mitigates the OCI.
e. If any such conflict of interest is found to exist, the FEDSIM CO may determine that the conflict cannot be avoided, neutralized, mitigated, or otherwise resolved to the satisfaction of the Government and the contractor may be found ineligible for award. Alternatively, the FEDSIM CO may determine that it is otherwise in the best interest of Government to contract with the contractor and include the appropriate provisions to avoid, neutralize, mitigate, or waiver such conflict in the contract awarded.

7.4.2 NON-DISCLOSURE REQUIREMENTS

If the contractor acts on behalf of, or provides advice with respect to any phase of an agency procurement, as defined in FAR 3.104-4, then the contractor shall execute and submit a Corporate Non-Disclosure Agreement (NDA) (Section 9 – List of Attachments, Attachment I) and ensure that all its personnel (to include subcontractors, teaming partners, and consultants) who will be personally and substantially involved in the performance of the TO:

a. Are listed on a signed Addendum to Corporate Non-Disclosure Agreement (NDA) Form (Section 9 – List of Attachments, Attachment I) prior to the commencement of any work on the TO,
b. Are instructed in the FAR 3.104 requirements for disclosure, protection, and marking of contractor bid or quote information, or source selection information, and
c. Are instructed in Far Part 9 for third party disclosures when acting in an advisory capacity.

All proposed replacement contractor personnel also must be listed on a signed Addendum to Corporate NDA and be instructed in the requirements of FAR 3.104. Any information provided by contractors in the performance of this TO or obtained by the Government is only to be used in the performance of the TO. The contractor shall put in place appropriate procedures for the protection of such information and shall be liable to the Government for any misuse or unauthorized disclosure of such information by its personnel, as defined above.

7.5 SECTION 508 COMPLIANCE REQUIREMENTS

Unless the Government invokes an exemption, all Electronic and Information Technology (EIT) products and services provided shall fully comply with Section 508 of the Rehabilitation Act of 1973, per the 1998 Amendments, 29 United States Code (U.S.C.) 794d, and the Architectural and Transportation Barriers Compliance Board's Electronic and Information Technology Accessibility Standards at 36 Code of Federal Regulations (CFR) 1194. The contractor shall identify all EIT products and services provided, identify the technical standards applicable to all products and services proposed, and state the degree of compliance with the applicable standards. Additionally, the contractor must clearly indicate where the information pertaining to Section 508 compliance can be found (e.g., Vendor's or other exact web page location). The contractor must ensure that the list is easily accessible by typical users beginning at time of award.

7.6 TRAVEL

No long distance travel is required.

7.7 COMMERCIAL SUPPLIER AGREEMENTS

7.8.1 The Government understands that commercial software tools that may be purchased in furtherance of this TO as described in Section 2.**5.3** and as contemplated in the Tools CLIN in Section 1.**2.1** (included with final RFQ) may be subject to commercial agreements which may take a variety of forms, including without limitation licensing agreements, terms of service, maintenance agreements, and the like, whether existing in hard copy or in an electronic or online format such as "clickwrap" or "browsewrap" (collectively, "Supplier Agreements"). For purposes of this TO, the Supplier Agreements are "collateral agreements" within the meaning of the FAR clause at 52.227-14.

7.8.2 The contractor shall ensure that any proposed Supplier Agreements allow the associated software and services to be used as necessary to achieve the objectives of this TO. The contractor shall provide all applicable Supplier Agreements to the FEDSIM CO prior to purchase and shall cooperate with the Government, including negotiations with the licensor as appropriate, to ensure compliance with this Section. Without limiting the generality of the foregoing, a compliant Supplier Agreement shall permit all of the following at no extra charge to the Government: (a) access and use by support contractors, including a successor contractor upon termination or expiration of this TO; (b) access and use by employees of other Federal, state and local law enforcement agencies; (c) transfer to a different data center and/or a successor contractor's cloud; and (d) the creation of derivative works that shall be subject to at least the same rights as set forth in subparagraphs (a) through (c) above. The above rights constitute "other rights and limitations" as contemplated in subparagraph (d) of the FAR clause at 52.227-14, Rights In Data – General (May 2014), Alternate III (Dec 2007).

7.9 NEWS RELEASE

The contractor shall not make any news release pertaining to this procurement without prior Government approval and only in coordination with the FEDSIM CO.

7.10 INTELLECTUAL PROPERTY RIGHTS

The existence of any patent, patent application, or other intellectual property right that encumbers any deliverable must be disclosed in writing on the cover letter that accompanies the delivery. If no such disclosures are provided, the data rights provisions in *(select applicable references and make sure the clauses are also listed in Section 8) or* FAR 52.227-14 apply.

8.1 FAR 52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This TO incorporates one or more clauses by reference with the same force and effect as if they were given in full text. Upon request, the CO will make their full text available. Also, the full text of a provision may be accessed electronically at:

FAR website: https://www.acquisition.gov/far/

Clause No	Clause Title	Date
52.203-13	Contractor Code of Business Ethics and Conduct	(Oct 2015)
52.203-14	Display of Hotline Posters (fill in or provide link to client's posters)	(Dec 2007)
52.203-17	Contractor Employee Whistleblower Rights and Requirement to Inform Employees of Whistleblower Rights	(Apr 2014)
52.204-2	Security Requirements	(Aug 1996)
52.204-7 (Provision)	System for Award Management	(Jul 2013)
52.204-9	Personal Identity Verification of Contractor Personnel	(Jan 2011)
52.204.10	Reporting Executive Compensation and First Tier Subcontract Awards	(Oct 2015)
52.204-13	System for Award Management Maintenance	(Jul 2013)
52.204-14	Service Contract Reporting Requirements	(Jan 2014)
52.215-22	Limitations on Pass-Through Charges- Identification of Subcontractor Effort	(Oct 2009)
52.215-23	Limitations on Pass-Through Charges	(Oct 2009)
52.219-8	Utilization of Small Business Concerns	(Oct 2014)
52.219-9	Small Business Subcontracting Plan	(Oct 2014)
52.224-1	Privacy Act Notification	(Apr 1984)
52.224-2	Privacy Act	(Apr 1984)
52.225-13	Restrictions on Certain Foreign Purchases	(Jun 2008)
52.227-14	Rights in Data – General	(Dec 2007)
52.227-14	Rights In Data – General Alternate II and III	(May 2014)
52.227-15	Representation of Limited Rights Data and Restricted Computer Software	(Dec 2007)
52.232-18	Availability of Funds	(Apr 1984)
52.232-40	Providing Accelerated Payment to Small Business Subcontractors (Deviation)	(Dec 2013)
52.239-1	Privacy or Security Safeguards	(Aug 1996)
52.244-6	Subcontracts for Commercial Items	(Apr 2015)

Clause No	Clause Title	Date
52.246-25	Limitation of Liability – Services	(Feb 1997)
52.247-14	Contractor Responsibility for Receipt of Shipment	(Apr 1984)
52.249-14	Excusable Delays	(Apr 1984)
52.251-1	Government Supply Sources	(Apr 2012)

8.2 GENERAL SERVICES ADMINISTRATION ACQUISITION MANUAL (GSAM) CLAUSES INCORPORATED BY REFERENCE

The full text of a provision may be accessed electronically at:

GSAM website: https://www.acquisition.gov/gsam/gsam.html

Clause No	Clause Title	Date
552.204-9	Personal Identity Verification Requirements	(Oct 2012)
552.236-75	Use of Premises	(Apr 1984)
552.239-70	Information Technology Security Plan and Security Authorization	(Jun 2011)
552.239-71	Security Requirements for Unclassified Information Technology Resources	(Jan 2012)
523.4	Use of Recovered Materials	
552.232.25	Prompt Payment	(Nov 2009)

8.3 PERFORMANCE

The Contractor shall ensure that development activities performed through this TO are in compliance with all Federal and FDA guidelines and practices including the following which are under change control:

- Food and Drug Administration (FDA) Enterprise Performance Life Cycle (EPLC)
  - http://inside.fda.gov:9003/it/ITGovernance/ITApplicationandDataStandards/default.htm
- DARRTS Boundary Document
  - https://svn.fda.gov/CDER/DARRTS/
- DARRTS Architecture
  - https://svn.fda.gov/CDER/DARRTS/
- DARRTS Data Model
  - https://svn.fda.gov/CDER/DARRTS/
- DARRTS System Requirements Specification
  - https://svn.fda.gov/CDER/DARRTS/

The following attachments are attached, either in full text or electronically at the end of the RFQ.

9.1 LIST OF ATTACHMENTS

Attachment	Title
A	Software Requirements Documentation Quality Review
B	Monthly Status Report
C	Quality Assurance Surveillance Plan
D	Problem Notification Report
E	Intentionally Left Blank
F	Intentionally Left Blank
G	COR Appointment Letter
H	Government Furnished Property
I	Corporate Non-Disclosure Agreement
J	Organizational Conflict of Interest (OCI) Statement

ATTACHMENT A

SOFTWARE REQUIREMENTS DOCUMENTATION QUALITY REVIEW

Software Requirements Documentation Quality Review

Score of 90% or greater represents acceptable quality

Organization and Completeness

	Are cross-references to other requirements correct?
	Are requirements written at a consistent and appropriate level of detail?
	Do the requirements provide an adequate basis for design?
	Is the implementation priority of each requirement included?
	Are all required hardware, software, and communication interfaces defined?
	Does the Requirements Document include known customer or system needs?
	Is any necessary information missing from a requirement? If so, is it identified as TBD?

Accuracy

	Do any requirements conflict with or duplicate other requirements?
	Is each requirement written in concise language?
	Is each requirement in scope for the project?
	Is each requirement free from content and grammatical errors?
	Can the requirements be implemented within known constraints?

Quality Attributes

	Are performance objectives specified?
	Are all security and safety considerations properly specified?
	Are other pertinent quality attribute goals explicitly documented and quantified, with the acceptable tradeoffs specified?

Traceability

	Is each requirement uniquely and correctly identified?
	Can each software functional requirement be traced to a higher-level requirement?

Special Issues

	Do the requirements align with the Boundary Document?
	Have all touch-points been identified?
	Are all requirements actually requirements, not design or implementation solutions?
	Are the time-critical functions identified, and timing criteria specified for them?
	Total Score: 0%

Scoring Scale

0	Deliverable does not address this area
1	5+ defects representing severe limitations or cost/schedule implications
2	< 5 defects representing severe limitations or cost/schedule implications
3	5+ defects representing moderate limitations or cost/schedule implications
4	< 5 defects representing moderate limitations or cost/schedule implications
5	Deliverable adequately addresses this area

ATTACHMENT B

MONTHLY STATUS REPORT FOR (MONTH AND YEAR)

Contractor Name
Task Order Number
Prepared by:
Reporting Period:
Page 1 of

Monthly Status Report

Work Planned for the Month

Work Completed During the Month

Work Not Completed During the Month

Work Planned for Next Month

Contract Meetings
Indicate the meeting date, meeting subject, persons in attendance and duration of the meeting.

Deliverable Status

Issues/Questions/Recommendations

Risks
Indicate potential risks, their probability, impact, and proposed mitigation strategy.

Funds/Hours Expended
Total hours expended by the contractor during the week. Total funds expended by the contractor during the week.

ATTACHMENT C

QUALITY ASSURANCE SURVEILLANCE PLAN (QASP)

Desired Outcomes	Performance/Quality Standard	Monitoring Method	Incentive
Deliverables (including shorter-term milestones if applicable) are received in accordance with the stated schedule parameters.	The stated delivery dates are met unless the Government and the Contractor agree to a new completion date.	100% inspection	Meeting or exceeding acceptable quality levels (AQL) will be used as input for annual performance assessment ratings
Releases are implemented in accordance within the timeframe of the stated schedule.	The stated delivery dates are met unless the Government and the Contractor agree to a new completion date.	100% inspection	Meeting or exceeding AQL will be used as input for annual performance assessment ratings
System Requirements Specification Document	Complies with inspection checklist at Appendix A, Software Requirements Documentation Quality Review.	100% inspection	Meeting or exceeding AQL will be used as input for annual performance assessment ratings
Testing completely addresses all requirements	1 or more test cases are documented and executed for each requirement.	100% Review of final Test report	Meeting or exceeding AQL will be used as input for annual performance assessment ratings
The number critical defects found in a release after being deployed to production shall low.	Not more than 3 high impact defects are found in a release after deployment.	100 % after 30 day period	Meeting or exceeding AQL will be used as input for annual performance assessment ratings
Overall customer satisfaction will be high	On a customer satisfaction survey scale of 1-5 the average satisfaction level will be 4 or higher	100% Review of Customer Satisfaction survey report	Meeting or exceeding AQL will be used as input for annual performance assessment ratings

SECTION 9 - LIST OF ATTACHMENTS

ATTACHMENT D

PROBLEM NOTIFICATION REPORT

TASK ORDER NUMBER: _____ DATE: _____

1. Nature and sources of problem:

2. COR was verbally notified on: (date) _____

3. Is action required by the Government? Yes_____No_____

4. If YES, describe Government action required and date required:

5. Will problem impact delivery schedule? Yes_____No_____

6. If YES, identify what deliverables will be affected and extent of delay:

7. Can required delivery be brought back on schedule? Yes_____No_____

8. Describe corrective action needed to resolve problems:

9. When will corrective action be completed?

10. Are increased costs anticipated? Yes_____No_____

11. Identify amount of increased costs anticipated, their nature, and define Government responsibility for problems and costs:

SECTION 9 - LIST OF ATTACHMENTS

ATTACHMENT E

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SECTION 9 - LIST OF ATTACHMENTS

SECTION 9 - LIST OF ATTACHMENTS

ATTACHMENT G

COR APPOINTMENT LETTER

Angela_Collum_CORL
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SECTION 9 - LIST OF ATTACHMENTS

ATTACHMENT H

GOVERNMENT FURNISHED PROPERTY

Tool Name	Primary Use
Business Objects	Develop reports
HP Quality Center	Test case management
Rational RequisitePro	Requirements management
Rational Performance Tester	Performance testing
JIRA / Tracker	Issue tracking
Subversion / Version Manager	Version control
Java, JavaScript, Java Server Pages, Extensible Mark-up Language (XML), Java Server Faces (JSF), User Interface XML (UIX), Service-Oriented architecture (SOA), Web Services etc.	Development
Adobe 10 or higher	Development
Microsoft Internet Explorer version 7 or higher	End user interface
Microsoft (MS) Office version 10 or higher	End user environment
Microsoft (MS) Word	Development
Microsoft (MS) Excel	Development
Microsoft (MS) PowerPoint	Presentations and communications
Microsoft (MS) Project	Project scheduling and reporting
Microsoft (MS) Visio	Diagramming and communications
Microsoft (MS) Access	Database
Documentum Foundation Classes/Equivalent as approved by FDA	Document management
Documentum WDK/Equivalent as approved by FDA	Document management
Documentum Content Rendition Services/Equivalent as approved by FDA	Document management
Documentum Administrator / Equivalent as approved by FDA	Document management
Oracle 11g	Database and application server environment
Eclipse and/or Oracle JDeveloper	Develop forms, libraries, and menus
TOAD/SQLDeveloper/SQL*Plus	Database tools
Oracle Designer / ERWIN	Database design
DROOLS Rules Engine	Automated business rules enforcement
AMP / InFocus / JAWS	Section 508 compliance testing tool
HP QuickTest Professional (QTP)	Automated testing tool

SECTION 9 - LIST OF ATTACHMENTS

Tool Name	Primary Use
Informatica	ETL tool
Apache JMeter	Automated performance testing tool
EMC2 Documentum eRoom / SharePoint	Collaboration tool
HP Service Center	Automated customer service requests tool
Clarity Corporate Performance Software	Program/project management and reporting
APEX	SQL tools
Appian	BPM tools

SECTION 9 - LIST OF ATTACHMENTS

ATTACHMENT I

NON-DISCLOSURE AGREEMENT
BETWEEN
U.S. GENERAL SERVICES ADMINISTRATION (GSA)
FEDERAL SYSTEMS INTEGRATION AND MANAGEMENT CENTER (FEDSIM)
AND
CSRA INTERNATIONAL, INC. (CSRA)

This agreement, made and entered into this_____day of_____, 2018 (the "Effective Date"), is by and between GSA and CSRA.

WHEREAS, CSRA and GSA FEDSIM have entered into GSCTFMGBPA090017, Task Order No. 47QFCA18K0065 for services supporting the FOOD AND DRUG ADMINISTRATION (FDA), DOCUMENT ARCHIVING REPORTING AND REGULATORY TRACKING SYSTEM (DARRTS) DATA MANAGEMENT AND ANALYSIS MODIFICATIONS, TO 29;

WHEREAS, CSRA is providing IT services under the Task Order;

WHEREAS, the services required to support DARRTS involve certain information which the Government considers to be "Confidential Information"[1] as defined herein;

WHEREAS, GSA desires to have CSRA's support to accomplish the Task Order services and, therefore, must grant access to the Confidential Information;

WHEREAS, CSRA through its work at a Government site may have access to Government systems or encounter information unrelated to performance of the Task Order which also is considered to be Confidential Information as defined herein;

WHEREAS, GSA on behalf of the FDA desires to protect the confidentiality and use of such Confidential Information;

NOW, THEREFORE, for and in consideration of the mutual promises contained herein, the parties agree as follows:

1. **Definitions.** "Confidential Information" shall mean any of the following: (1) "contractor bid or proposal information" and "source selection information" as those terms are defined in 41 U.S.C. § 2101; (2) the trade secrets or proprietary information of other companies; (3) other information, whether owned or developed by the Government, that has not been previously made available to the public, such

[1] This does not denote an official security classification.

as the requirements, funding or budgeting data of the Government; and *for contracts/orders providing acquisition assistance,* this term specifically includes (4) past performance information, actual/proposed costs, overhead rates, profit, award fee determinations, contractor employee data of offerors/contractors, methods or procedures used to evaluate performance, assessments, ratings or deliberations developed in an evaluation process, the substance of any discussions or deliberations in an evaluation process, and any recommendations or decisions of the Government unless and until such decisions are publicly announced. This term is limited to unclassified information.

2. **Limitations on Disclosure.** CSRA agrees (and the CSRA Task Order personnel must agree by separate written agreement with CSRA) not to distribute, disclose or disseminate Confidential Information to anyone beyond the personnel identified in the [ATTACHED ADDENDUM], unless authorized in advance by the GSA Contracting Officer in writing. The Contracting Officer and FDA TPOC will review the Addendum to ensure it includes only those individuals to be allowed access to the information. The Addendum, which may be updated from time to time, is approved when signed by the GSA Contracting Officer and the FDA TPOC.

3. **Agreements with Employees and Subcontractors.** CSRA will require its employees and any subcontractors or subcontractor employees performing services for this Task Order to sign non-disclosure agreements obligating each employee/subcontractor employee to comply with the terms of this agreement. CSRA shall maintain copies of each agreement on file and furnish them to the Government upon request.

4. **Statutory Restrictions Relating to Procurement Information.** CSRA acknowledges that certain Confidential Information may be subject to restrictions in Section 27 of the Office of Federal Procurement Policy Act (41 U.S.C. § 2104), as amended, and disclosures may result in criminal, civil, and/or administrative penalties. In addition, CSRA acknowledges that 18 U.S.C. § 1905, a criminal statute, bars an employee of a private sector organization from divulging certain confidential business information unless authorized by law.

5. **Limitations on Use of Confidential Information.** CSRA may obtain Confidential Information through performance of the Task Order orally or in writing. These disclosures or this access to information is being made upon the basis of the confidential relationship between the parties and, unless specifically authorized in accordance with this agreement, CSRA will:
   a) Use such Confidential Information for the sole purpose of performing the DARRTS support requirements detailed in the Task Order and for no other purpose;
   b) Not make any copies of Confidential Information, in whole or in part;

c) Promptly notify GSA in writing of any unauthorized misappropriation, disclosure, or use by any person of the Confidential Information which may come to its attention and take all steps reasonably necessary to limit, stop or otherwise remedy such misappropriation, disclosure, or use caused or permitted by a CSRA employee.

6. **Duties Respecting Third Parties.** If CSRA will have access to the proprietary information of other companies in performing Task Order support services for the Government, CSRA shall enter into agreements with the other companies to protect their information from unauthorized use or disclosure for as long as it remains proprietary and refrain from using the information for any purpose other than that for which it was furnished. CSRA agrees to maintain copies of these third party agreements and furnish them to the Government upon request in accordance with 48 C.F.R. § 9.505-4(b).

7. **Notice Concerning Organizational Conflicts of Interest.** CSRA agrees that distribution, disclosure or dissemination of Confidential Information (whether authorized or unauthorized) within its corporate organization or affiliates, may lead to disqualification from participation in future Government procurements under the organizational conflict of interest rules of 48 C.F.R. § 9.5.

8. **Entire Agreement.** This Agreement constitutes the entire agreement between the parties and supersedes any prior or contemporaneous oral or written representations with regard to protection of Confidential Information in performance of the subject Task Order. This Agreement may not be modified except in writing signed by both parties.

9. **Governing Law**. The laws of the United States shall govern this agreement.

10. **Severability.** If any provision of this Agreement is invalid or unenforceable under the applicable law, the remaining provisions shall remain in effect.

In accordance with Public Law No. 108-447, Consolidated Act, 2005, the following is applicable:

> These restrictions are consistent with and do not supersede, conflict with, or otherwise alter the employee obligations, rights, or liabilities created by Executive Order No. 12958; section 7211 of title 5, United States Code (governing disclosures to Congress); section 1034 of title 10, United States Code, as amended by the Military Whistleblower Protection Act (governing disclosure to Congress by members of the military); section 2302(b)(8) of title 5, United States Code, as amended by the Whistleblower Protection Act (governing disclosures of illegality, waste, fraud, abuse or public health or safety threats); the Intelligence Identities Protection Act of 1982 (50 U.S.C. 421 et seq.) (governing disclosures

that could expose confidential Government agents); and the statutes which protect against disclosure that may compromise the national security, including sections 641, 793, 794, 798, and 952 of title 18, United States Code, and section 4(b) of the Subversive Activities Act of 1950 (50 U.S.C. 783(b)). The definitions, requirements, obligations, rights, sanctions, and liabilities created by said Executive order and listed statutes are incorporated into this agreement and are controlling.

11. **Beneficiaries.** If information owned by an individual or entity not a party to this agreement is disclosed or misappropriated by CSRA in breach of this agreement, such information owner is a third party beneficiary of this agreement. However, nothing herein shall create an independent right of action against the U.S. Government by any third party.

IN WITNESS WHEREOF, GSA and CSRA have caused the Agreement to be executed as of the day and year first written above.

UNITED STATES GENERAL SERVICES ADMINISTRATION

_____ _____
Name Date

_____
Contracting Officer

CSRA

_____ _____
Name* Date

_____
Title

*Person must have the authority to bind the company

SECTION 9 - LIST OF ATTACHMENTS

ATTACHMENT J

ORGANIZATIONAL CONFLICT OF INTEREST (OCI) STATEMENT

The offeror and each subcontractor, consultant, and/or teaming partner shall complete and sign an Organizational Conflict of Interest (OCI) Statement. All information pertaining to OCI is outlined in Section 7.4.1.

The contractor shall represent either that:

1. It is not aware of any facts that create any actual or potential OCI relating to the award of this contract, or
2. It has included information in its proposal, providing all current information bearing on the existence of any actual or potential OCI.

If a contractor with an actual or potential OCI believes the conflict can be avoided, neutralized, or mitigated, the contractor shall submit a mitigation plan to the Government for review.

Definition: FAR 2.101 “Organizational conflict of interest” means that because of other activities or relationships with other persons, a person is unable or potentially unable to render impartial assistance or advice to the Government, or the person’s objectivity in performing the contract work is or might be otherwise impaired, or a person has an unfair competitive advantage.

SAMPLE 1 – OFFEROR OCI STATEMENT

The following is an example of the OCI statement that each offeror shall complete and sign. All information pertaining to OCI is outlined in Section 7.4.1.

(Insert Offeror Name) is performing services in support of the Food and Drug Administration, TO 29. In accordance with solicitation Section 7.4.1 *(Inset Offeror Name)* has reviewed the requirements and the Federal Acquisition Regulation (FAR) Subpart 9.5.

(Insert Offeror Name) is not aware of any facts which create any actual or potential OCI relating to the award of this contract. *(Insert Offeror Name)* agrees to immediately disclose all information concerning any actual or potential OCI during the performance of the Task Order.

Insert Offeror Name

_____ _____

*Insert Offeror Point of Contact (POC) Name** Date

_____

POC Title

*Person must have the authority to bind the company.

SAMPLE 2 – SUBCONTRACTOR, CONSULTANT, TEAMING PARTNER OCI STATEMENT

The following is an example of the OCI statement that each subcontractor, consultant, and teaming partner shall complete and sign. All information pertaining to OCI is outlined in Section 7.4.1.

(Insert Offeror Name) is performing services in support of the Food and Drug Administration, TO 29. In accordance with solicitation Section 7.4.1 *(Inset Offeror Name)* has reviewed the requirements and the Federal Acquisition Regulation (FAR) Subpart 9.5.

(Insert Company Name) is not aware of any facts which create any actual or potential OCI relating to the award of this contract. *(Insert Company Name)* agrees to immediately disclose all information concerning any actual or potential OCI during the performance of the Task Order.

Subcontractor, Consultant, Teaming Partner

_____ _____

*Point of Contact (POC) Name** Date

_____

POC Title

*Person must have the authority to bind the company.